

## Overview

Breakthrough developments in the Medical Device (MedTech) sector present investment opportunities for investors who understand which catalyst events to monitor. Filing a PMA (Premarket Approval Application) with the FDA is one of the most important catalysts for any MedTech company, much like the filing of an NDA (New Drug Application) for a drug company.

In order to file a PMA with the FDA, the device needs to be classified as a Class III Medical Device. These devices are generally high value and technology driven products that require extensive clinical trials and are protected by patents. Heart valves, pacemakers, silicone breast implants, hip and knee replacement systems and drug-eluting stents are examples of the better known Class III Medical Devices.

This report takes advantage of Revere's proprietary classification system and comprehensive company coverage to identify Medical Device companies with PMAs pending FDA approval. Key company-specific information includes:

- Device tradenames and indications
- Estimated approval dates
- Competitive landscape of the products
- Potential market size of the products
- Approval impact ranking

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### Notes:

- a) Revere estimated approval timeframes are based on historic average time to approval for Premarket Applications (PMA).
- b) Devices developed by private firms or companies not traded publicly in the U.S. are excluded from this analysis.

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## 1. Companies with Pending PMA Filings

| Companies with Expected PMA Approvals in 2007 / 2008 |                                      |
|--|--------------------------------------|
| Abbott Laboratories (ABT)                            | <b>Medtronic, Inc. (MDT) [5]</b>     |
| ABIOMED, Inc. (ABMD)                                 | <b>Mentor Corporation (MNT) [2]</b>  |
| Allergan, Inc. (AGN)                                 | sanofi-aventis (SNY)                 |
| Angiotech Pharmaceuticals, Inc. (ANPI)               | Smith & Nephew plc (SNN)             |
| ATS Medical, Inc. (ATSI)                             | STAAR Surgical Company (STAA)        |
| Boston Scientific Corp (BSX)                         | <b>Stryker Corporation (SYK) [2]</b> |
| BSD Medical Corporation (BSM)                        | ThermoGenesis Corp. (KOOL)           |
| CryoCor, Inc. (CRYO)                                 | Thoratec Corporation (THOR)          |
| DexCom, Inc. (DXCM)                                  | Wright Medical Group (WMGI)          |
| <b>Johnson &amp; Johnson (JNJ) [2]</b>               |                                      |

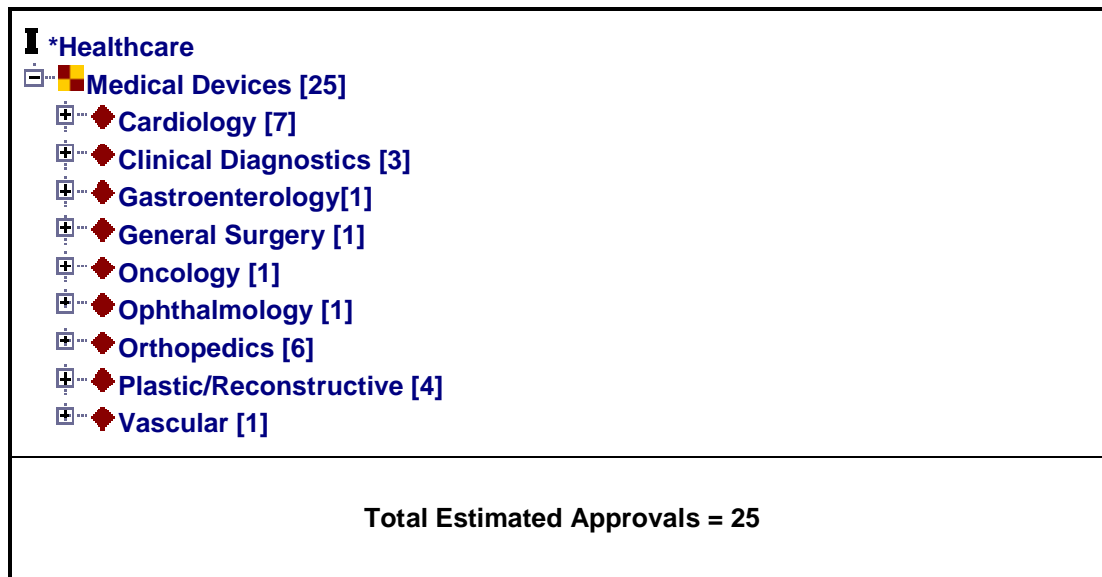
**Notes:** 1. Companies with more than one PMA are shown in **bold** with the number of PMA in brackets [ ].

2. Some PMAs are jointly owned by more than one company through licensing agreements.

According to Revere, there are approximately **247** U.S. publicly traded MedTech companies. As can be seen from the above table, less than 10% of them have active PMAs under FDA review. This statistic conveys 3 important pieces of insight:

- **Innovative, groundbreaking MedTech developments take place only in a small % of MedTech companies**
- **Discovering exceptional MedTech investments means looking for those who have maintained a successful track record of filing PMAs and gaining FDA approvals**
- **Small to Mid-Cap MedTech companies who are able to pass all the clinical and regulatory hurdles involved in filing PMAs have the greatest potential for explosive growth**

## 2. PMA Filings by Sector\*



\*Based on Revere's proprietary and patented industry classification system

Revere classifies the Medical Device sector into 21 sub-sectors, with each facing a different set of market opportunities, product innovations and life cycle, and competitive dynamics. Success in MedTech investment, therefore, hinges greatly on finding the right balance of sub-sectors with growing market opportunities, breakthrough innovations, and moderate competitive intensity.

In this report, 25 PMA filings have been identified and analyzed, with Cardiology, Orthopedic, and Plastic/Reconstructive accounting for 7, 6, and 4 PMA filings respectively. Generally, the greater the number of PMA filings within a subsector, the more likely that it is a rapidly growing market with a healthy pipeline of breakthrough products. While competition is intense on the surface for all 3 subsectors, the true gauge of competitive intensity depends on the specific devices being developed. The following section details important factors related to the potential impact of each device.

### 3. Estimated PMA Approvals in 2007/2008

| Company (Symbol)   | Class III Device Candidate                                    | Indication  | Estimated Approval Date* | Device Will Compete with Three or Fewer Similar Devices if Approved?                            | 1st or 2nd Class III Approved Device of the Company? | Estimated Market Size (M=Million, B=Billion) |
|--|---|---|--------------------------|---|--|--|
| <b>DexCom, Inc. (DXCM)</b>   | Dexcom Next Generation STS Glucose Monitoring System          | Non-Invasive continuous glucose monitoring  | <b>May 2007</b>          | No—Multiple   | Yes  | \$1-3B                                       |
| <b>Medtronic, Inc. (MDT)</b>   | Prestige ST Cervical Disc System                              | Total cervical disc replacement for degenerative disc disease   | <b>May 2007</b>          | Yes—Ant-Cer (ABT), SC-AcuFix (ABT), Tether System (SYK)   | No   | \$300-400M                                   |
| <b>Smith &amp; Nephew plc (SNN)</b>  | DUROLANE (In-licensed from Q-MED AB)                          | Single injection hyaluronic acid therapy for the treatment of osteoarthritis (OA) of the hip and knee | May 2007                 | Yes—Hyalgan (SNY), Orthovisc (ANIK), Synvisc (GENZ)   | No   | \$450M                                       |
| <b>Abbott Laboratories (ABT)</b>   | FreeStyle Navigator Continuous Glucose Monitoring System      | Continuous blood glucose monitoring   | Q2:2007                  | No--Multiple  | No   | \$1-3B                                       |
| <b>Johnson &amp; Johnson (JNJ)</b>   | Veridex GeneSearch BLN Assay                                  | Intra-operative detection of breast cancer metastases using real-time PCR                             | <b>Q2:2007</b>           | No—Multiple   | No   | \$100-300M                                   |
| <b>BSD Medical Corporation (BSM)</b>   | BSD-2000 Cancer Treatment System                              | Thermotherapy treatment of cancer tumors deep within the body tissue                                  | July 2007                | Yes—Only device available for this indication   | Yes  | \$1-2B                                       |
| <b>sanofi-aventis (SNY)</b>  | Sculptra (Injectable Poly-L-Lactic Acid)                      | Cosmetic facial filler  | July 2007                | Yes—Only polymer-based injectable product for this indication                                   | No   | \$350-500M                                   |
| <b>CryoCor, Inc. (CRYO)</b>  | CryoCor Cardiac Cryoablation System                           | Atrial flutter  | <b>August 2007</b>       | Yes—FrostByte (ATSI), Surgi-Frost (ATSI)  | Yes  | \$400M                                       |
| <b>ABIOMED, Inc. (ABMD)</b>  | iPulse  | Intra-Aortic balloon pump console for treatment of diminished heart function/ temporary heart failure | <b>Q3:2007</b>           | Yes—Only device available for this indication   | No   | \$200M                                       |
| <b>Allergan, Inc. (AGN)</b>  | Style 410 Bio-Dimensional Cohesive Gel Matrix Breast Implants | Silicone gel-filled breast implants   | Q3:2007                  | Yes—MemoryGel (MNT), Contour Profile Gel (MNT)  | No   | \$350-400M                                   |
| <b>Boston Scientific Corp (BSX) / Angiotech Pharmaceuticals, Inc. (ANPI)</b> | TAXUS Liberte (Paclitaxel-Eluting Coronary Stent)             | Restenosis prevention/ coronary artery disease  | Q3:2007                  | Yes—Cordis CYPHER Sirolimus Eluting Stent (JNJ/GDT), Endeavor Drug-Eluting Coronary Stent (MDT) | No   | \$4-5B                                       |

|                                      |  |  |                 |   |     |              |
|--------------------------------------|--|--|-----------------|---|-----|--------------|
| <b>Medtronic, Inc (MDT)</b>          | Endeavor Drug Eluting Coronary Stent System        | Restenosis prevention/ coronary artery disease                               | <b>Q3:2007</b>  | Yes— Cordis CYPHER (JNJ/GDT), TAXUS Liberte (BSX/ANPI)                                | No  | \$4-5B       |
| <b>Mentor Corporation (MNT)</b>      | Contour Profile Gel Silicone Breast Implants       | Silicone gel-filled breast implants for breast augmentation / reconstruction | Q3:2007         | Yes—Round Silicone Implants (AGN), Style 410 Implants (AGN)                           | No  | \$350-400M   |
| <b>Medtronic, Inc (MDT)</b>          | Carotid Solution System                            | Carotid artery disease / stroke prevention                                   | <b>Q4:2007</b>  | No—Multiple   | No  | \$150-\$250M |
| <b>ATS Medical, Inc. (ATSI)</b>      | 3F Aortic Bioprosthesis Heart Valve                | Aortic stenosis / aortic valve diseases                                      | <b>Q4:2007</b>  | No—Multiple   | No  | \$500M       |
| <b>Stryker Corporation (SYK)</b>     | Cormet Hip Resurfacing System                      | Hip joint replacement  | Q4:2007         | Yes—Birmingham Hip Resurfacing System (SNN), Conserve Plus Resurfacing Implant (WMGI) | No  | \$300-550M   |
| <b>ThermoGenesis Corp. (KOOL)</b>    | CryoSeal Fibrin Sealant (FS) System                | Autologous fibrin hemostatic sealant production and delivery                 | Q4:2007         | No—Multiple   | Yes | \$450-500M   |
| <b>Thoratec Corporation (THOR)</b>   | HeartMate II Left Ventricular Assist System (LVAS) | Bridge-to-Transplantation for heart transplant patients                      | Q4:2007         | Yes—Novacor LVAS (WHRT)   | No  | \$100M       |
| <b>Wright Medical Group (WMGI)</b>   | CONSERVE Plus Hip Resurfacing Implant              | Hip joint replacement  | Q4:2007         | Yes—Cormet System (SYK), Birmingham Hip Resurfacing System (SNN)                      | No  | \$300-550M   |
| <b>Medtronic, Inc (MDT)</b>          | Amplify rh-BMP-2 Matrix                            | Posterior lumbar spinal fusion for degenerative disc disease                 | <b>2H:2007</b>  | No—Multiple   | No  | \$500-700M   |
| <b>Medtronic, Inc (MDT)</b>          | Talent Thoracic Stent                              | Thoracic aneurysm  | Q1:2008         | Yes—Only device available for this indication   | No  | \$250-350M   |
| <b>Mentor Corporation (MNT)</b>      | Puragen Plus                                       | Skin augmentation and wrinkles correction                                    | <b>May 2008</b> | No—Multiple   | No  | \$400-500M   |
| <b>STAAR Surgical Company (STAA)</b> | Visian TICL  | Myopia (Nearsightedness) and astigmatism                                     | <b>1H:2008</b>  | Yes—Only device available for this indication   | No  | \$4-5B       |
| <b>Johnson &amp; Johnson (JNJ)</b>   | Adjustable Gastric Band (AGB)                      | Treatment of morbid obesity  | July 2008       | Yes—Bioentereics Lap-Band/Lap-Band VG Systems (AGN), EASYBAND Remote System (AGN)     | No  | \$200M       |
| <b>Stryker Corporation (SYK)</b>     | OP-1 Implant                                       | Posterolateral lumbar spine fusion   | Q4:2008         | Yes—INFUSE Matrix (MDT), AMPLIFY Matrix (MDT)   | No  | \$500-700M   |

\* Dates in **bold** indicate that Revere has confirmed directly with the company or indirectly through company filings and press releases. Revere estimates are based on PMA (Premarket Approval) Application submission dates, historic time-to-approval averages, and other available information.

## 4. Approval Impact Ranking

While knowing the estimated market size provides a good framework for analyzing the individual device's revenue potential, it does not address the likely impact to the company's stock price if its PMA is approved. The following table calculates an Estimated Market Size/Market Cap. Ratio for each company and ranks them in decreasing order. This ratio is meant to approximate the impact of a PMA approval to the company's stock price—the greater the ratio, the bigger the impact on the stock price.

| Company (Ticker)                              | Class III Device Candidate                         | Market Cap. (M)* | Est. Market Size (M=Million, B=Billion) | Est. Market Size / Market Cap. Ratio |
|---|--|------------------|---|--------------------------------------|
| <b>STAAR Surgical Company (STAA)</b>          | Visian TICL  | \$144M           | \$4-5B                                  | <b>27.8-34.7</b>                     |
| <b>Angiotech Pharmaceuticals, Inc. (ANPI)</b> | TAXUS Liberte (Paclitaxel-Eluting Coronary Stent)  | \$557M           | \$4-5B                                  | <b>7.2-9.0</b>                       |
| <b>BSD Medical Corporation (BSM)</b>          | BSD-2000 Cancer Treatment System                   | \$148M           | \$1-2B                                  | <b>6.8-13.5</b>                      |
| <b>ATS Medical, Inc. (ATSI)</b>               | 3F Aortic Bioprosthesis Heart Valve                | \$83M            | \$500M                                  | <b>6.0</b>                           |
| <b>CryoCor, Inc. (CRYO)</b>                   | Cardiac Cryoablation System                        | \$69M            | \$400M                                  | <b>5.8</b>                           |
| <b>DexCom, Inc. (DXCM)</b>                    | Next Generation STS Monitoring System              | \$209M           | \$1-3B                                  | <b>4.8-14.4</b>                      |
| <b>ThermoGenesis Corp. (KOOL)</b>             | CryoSeal Fibrin Sealant (FS) System                | \$182M           | \$450-500M                              | <b>2.5-2.7</b>                       |
| <b>Wright Medical Group (WMGI)</b>            | CONSERVE Plus Hip Resurfacing Implant              | \$899M           | \$300-550M                              | <b>0.33-0.61</b>                     |
| <b>ABIOMED, Inc. (ABMD)</b>                   | iPulse   | \$416M           | \$100-200M                              | <b>0.24-0.48</b>                     |
| <b>Mentor Corporation (MNT)</b>               | MemoryGel Silicone Gel Breast Implant              | \$1,734M         | \$350-400M                              | <b>0.20-0.23</b>                     |
|   | Puragen Plus                                       |                  | \$400-500M                              | <b>0.23-0.29</b>                     |
| <b>Boston Scientific Corp (BSX)</b>           | TAXUS Liberte (Paclitaxel-Eluting Coronary Stent)  | \$23,953M        | \$4-5B                                  | <b>0.17-0.21</b>                     |
| <b>Thoratec Corporation (THOR)</b>            | HeartMate II Left Ventricular Assist System (LVAS) | \$988M           | \$100M                                  | <b>0.10</b>                          |
| <b>Medtronic, Inc (MDT)</b>                   | Endeavor Drug Eluting Coronary Stent System        | \$61,827M        | \$4-5B                                  | <b>0.065-0.081</b>                   |
|   | Amplify rh-BMP-2 Matrix                            |                  | \$500-700M                              | <b>0.0081-0.011</b>                  |
|   | Carotid Solution System                            |                  | \$150-200M                              | <b>0.0024-0.0032</b>                 |
|   | Prestige ST  |                  | \$300-400M                              | <b>0.0049-0.0065</b>                 |
|   | Talent Thoracic Stent                              |                  | \$250-350M                              | <b>0.0040-0.0057</b>                 |
| <b>Smith &amp; Nephew plc (SNN)</b>           | DUROLANE   | \$11,693M        | \$450M                                  | <b>0.038</b>                         |

|                                    |  |            |            |                       |
|------------------------------------|--|------------|------------|-----------------------|
| <b>Allergan, Inc. (AGN)</b>        | Style 410 Breast Implants                                | \$18,453M  | \$350-400M | <b>0.019-0.022</b>    |
| <b>Stryker Corporation (SYK)</b>   | Cormet Hip Resurfacing System                            | \$26,942M  | \$300-550M | <b>0.011-0.020</b>    |
|                                    | OP-1 Implant   |            | \$500-700M | <b>0.019-0.026</b>    |
| <b>Abbott Laboratories (ABT)</b>   | FreeStyle Navigator Continuous Glucose Monitoring System | \$89,961M  | \$1-3B     | <b>0.011-0.033</b>    |
| <b>sanofi-aventis (SNY)</b>        | Sculptra   | \$126,183M | \$350-500M | <b>0.0028-0.0040</b>  |
| <b>Johnson &amp; Johnson (JNJ)</b> | Adjustable Gastric Band (AGB)                            | \$186,667M | \$200M     | <b>0.0011</b>         |
|                                    | Veridex GeneSearch BLN                                   |            | \$100-300M | <b>0.00054-0.0016</b> |

\*Market cap. based on closing stock price on 5/4/2007

## 5. Approved PMA from May 06 MedTech PMA Pipeline Report

| Company (Symbol)                | Device PMA Approved                              | Indication   | FDA Approval Date vs. Revere Report Estimate | Estimated Market Size / Market Cap. Ratio | % Return Since Approval* | % Return Since May 2006** |
|---------------------------------|--|--|--|---|--------------------------|---------------------------|
| Allergan, Inc. (AGN)            | Juvederm   | Dermal filler for wrinkle removal and other skin augmentation            | 6/5/2006 vs. 2/2007                          | 0.03-0.04                                 | +22.9%                   | +25.8%                    |
|                                 | Inamed Round Silicone Gel-Filled Breast Implants | Silicone breast implants   | 11/17/2006 vs. 12/2006                       | 0.026-0.031                               | +7.8%                    |                           |
| St. Jude Medical, Inc. (STJ)    | Proxis Embolic Protection System                 | Embolism protection during percutaneous coronary intervention procedures | 9/13/2006 vs. 5/2006                         | 0.02-0.03                                 | +18.5%                   | +21.7%                    |
| Johnson & Johnson (JNJ)         | Cordis Precise Nitinol Carotid Stent System      | Carotid artery disease restenosis prevention                             | 9/26/2006 vs. 11/2006                        | 0.0010-0.0013                             | -0.29%                   | +7.2%                     |
| Uroplasty, Inc. (UPI)           | Macroplastique Implantation System               | Tissue bulking agents for female urinary incontinence                    | 10/31/2006 vs. Late 2007                     | 7-14                                      | +42.0%                   | 73.9%                     |
| Mentor Corporation (MNT)        | MemoryGel Silicone Gel Breast Implant            | Silicone breast implants   | 11/17/2006 vs. Early 2007                    | 0.18-0.21                                 | -14.2%                   | +5.3%                     |
| Possis Medical, Inc. (POSS)     | AngioJet Ultra Console                           | Thrombus (Blood Clot) removal from arteries and veins                    | 12/18/2006 vs. 7/2006                        | 1-2                                       | +2.2%                    | +36.4%                    |
|                                 | AngioJet SpiroFlex Catheter                      | Thrombus (Blood Clot) removal from arteries and veins                    | 1/30/2007 vs. 10/2006                        |   | -1.1%                    |                           |
| Anika Therapeutics, Inc. (ANIK) | REDEFYNE   | Hyaluronic acid for dermal defects (fine lines, folds, scars)            | 12/21/2006 vs. 11/2006                       | 3-4                                       | -2.5%                    | +25.3%                    |
| ev3 Inc. (EVVV)                 | Protégé Stent/ SpideRX                           | Carotid artery disease restenosis prevention                             | 1/24/2007 vs. 12/2006                        | 0.2-0.3                                   | +1.0%                    | +25.7%                    |

\*% Return is calculated based the closing price on the date of FDA approval to the closing price on 5/4/2007.

\*\*% Return is calculated based the closing price on 5/18/2006 to the closing price on 5/4/2007.

## 6. Price and Financial Info

Data as of May 8, 2007

| Company (Symbol)                       | Last Price | Market Cap. (M) | 30-Day Avg. Volume | 1-Year Return | Relative Performance vs. Revere Biopharm Index | Estimated Market Size / Market Cap Ratio | Average Analyst Rating / # of Analyst Coverage | Options Available? |
|--|------------|-----------------|--------------------|---------------|--|--|--|--------------------|
| Abbott Laboratories (ABT)              | 58.84      | 90,794          | 5,830,976          | 38.5%         | 29.3%  | 0.011-0.033                              | 1.64 / 11                                      | YES                |
| ABIOMED, Inc. (ABMD)                   | 12.44      | 401             | 155,468            | -9.4%         | -18.6%   | 0.24-0.48                                | 2 / 2  | YES                |
| Allergan, Inc. (AGN)                   | 123.64     | 18,808          | 942,404            | 27.4%         | 18.2%  | 0.019-0.022                              | 1.83 / 9                                       | YES                |
| Angiotech Pharmaceuticals, Inc. (ANPI) | 6.85       | 582             | 1,222,364          | -53.4%        | -62.6%   | 7.2-9.0                                  | 2 / 10   | YES                |
| ATS Medical, Inc. (ATSI)               | 1.60       | 78              | 111,065            | -46.3%        | -55.5%   | 6.0                                      | 2 / 3  | NO                 |
| Boston Scientific Corp. (BSX)          | 16.58      | 24,576          | 13,388,356         | -24.4%        | -33.6%   | 0.17-0.21                                | 2.46 / 13                                      | YES                |
| BSD Medical Corporation (BSM)          | 6.96       | 147             | 89,845             | 15.6%         | 6.4%   | 6.8-13.5                                 | N/A  | YES                |
| CryoCor, Inc. (CRYO)                   | 6.50       | 72              | 19,509             | 182.6%        | 173.4%   | 5.8                                      | 3 / 1  | NO                 |
| DexCom, Inc. (DXCM)                    | 7.40       | 210             | 269,708            | -69.9%        | -79.1%   | 4.8-14.4                                 | 2 / 6  | YES                |
| Johnson & Johnson (JNJ)                | 63.70      | 184,409         | 11,767,292         | 8.5%          | -0.7%  | 0.0016-0.0027                            | 1.85 / 13                                      | YES                |
| Medtronic, Inc. (MDT)                  | 53.43      | 61,528          | 6,098,728          | 11.2%         | 2.0%   | 0.084-0.11                               | 1.81 / 16                                      | YES                |
| Mentor Corporation (MNT)               | 40.78      | 1,732           | 1,484,640          | -6.1%         | -15.3%   | 0.43-0.59                                | 2.56 / 9                                       | YES                |
| sanofi-aventis (SNY)                   | 46.47      | 126,346         | 1,477,752          | -2.8%         | -12.0%   | 0.0028-0.0040                            | 2.67 / 6                                       | YES                |
| Smith & Nephew plc (SNN)               | 61.97      | 11,639          | 74,122             | 52.3%         | 43.1%  | 0.038                                    | 2.5 / 8  | NO                 |
| STAAR Surgical Company (STAA)          | 5.19       | 150             | 146,084            | -42.3%        | -51.5%   | 27.8-34.7                                | 2 / 1  | YES                |
| Stryker Corporation (SYK)              | 65.61      | 26,840          | 1,714,256          | 49.7%         | 40.5%  | 0.030-0.046                              | 2.25 / 16                                      | YES                |
| ThermoGenesis Corp. (KOOL)             | 3.52       | 194             | 247,262            | -13.5%        | -22.7%   | 2.5-2.7                                  | 1 / 1  | NO                 |
| Thoratec Corporation (THOR)            | 18.17      | 966             | 905,553            | 8.5%          | -0.7%  | 0.10                                     | 1.6 / 5  | YES                |
| Wright Medical Group, Inc. (WMGI)      | 25.08      | 886             | 350,982            | 9.4%          | 0.2%   | 0.033-0.061                              | 2 / 11   | YES                |

\*Average Analyst Rating range from 1 to 5, with 1=Strong Buy, 2=Buy, 3=Hold, 4=Sell, 5=Strong Sell

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